

EXHIBIT 1



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August 7, 2024

Applied Therapeutics

2Q24: Accel Approval Path for SORD, Galactosemia Reanalysis Positive, See Favorable NT Regulatory Setup

Our view: APLT reported 2Q24 earnings and we had a chance to catch up with the mgmt team. With a favorable data reanalysis and coming off the positive recent AdComm for a drug in the same division, we see favorable tailwinds for govorestat in galactosemia into the Oct 9 panel and Nov 28 PDUFA, and confirmation of an accelerated approval path in SORD deficiency is a win that could enable them to expand into an even larger indication more rapidly. While we acknowledge uncertainties around how a panel will view their drug vs. ZVRA's, data reliability given the reassessment, and complexity of a confirmatory SORD study, on balance we see a favorable setup and would be buyers into key 2H regulatory events, especially given govorestat's \$700M LT opportunity.

Key points:

Financials: R&D was \$10.0M, lower than our \$12.8M est, with SG&A at \$10.6M, in line with our \$10.9M expectations. Cash and cash equivalents were \$122.2M, which the company expects to fund operations into 2026.

SORD accelerated approval path confirmed following FDA minutes, will likely involve separate confirmatory study. Following receipt of the meeting minutes, APLT confirmed that FDA is on board with filing for accelerated approval in SORD deficiency based on the existing data package showing sorbitol reductions and correlations to 10MWR - demonstrating a very surmountable initial approval bar, in our view, following sNDA submission early-1Q (following galactosemia approval). We believe the potential for AA filing underscores the FDA's flexibility on using biomarkers and correlations to functional measures in rare diseases, though the likely need for a separate subsequent confirmatory study with FDA's apparent preference for the 10MWR endpoint (where the drug performed less well) may add some very long-term risk. We believe SORD represents a \$400M LT opportunity in outyears.

Reanalysis of cognition endpoint net positive for galactosemia filing package, though may perpetuate some bear concerns around data reliability. The company announced corrections to the formula used for their cognition and motor skill scores (initially had used adult, vs pediatric formula) from the ph.III galactosemia trial, resulting in improvement on a sensitivity analysis of the primary endpoint including cognition (cognition turned stat. sig.) We believe this may incrementally strengthen APLT's data package in anticipation of their AdComm - especially given GeMDAC's recent emphasis of the importance of cognition for a recently reviewed drug. While this delayed error identification may lead to questions about whether there may be additional mistakes in the rest of the data package (recall data integrity and presentation had been a concern for some),

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Outperform

Speculative Risk

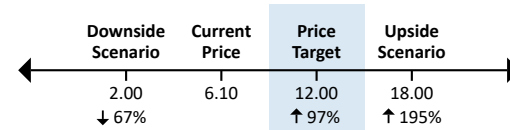
NASDAQ: APLT; USD 6.10

Price Target USD 12.00

WHAT'S INSIDE

<input type="checkbox"/> Rating/Risk Change	<input type="checkbox"/> Price Target Change
<input type="checkbox"/> In-Depth Report	<input checked="" type="checkbox"/> Est. Change
<input type="checkbox"/> Preview	<input checked="" type="checkbox"/> News Analysis

Scenario Analysis*



*Implied Total Returns

Key Statistics

Shares O/S (MM):	143.9	Market Cap (MM):	878
Dividend:	0.00	Yield:	0.0%
		Avg. Daily Volume:	1,388,910

RBC Estimates

FY Dec	2023A	2024E	2025E	2026E
Revenue	10.0	0.6	55.0	187.7
Prev.		2.0	58.9	191.6
EPS, Ops Diluted	(1.42)	(0.93)	(0.56)	0.18
Prev.		(1.19)	(0.57)	0.19
P/E	NM	NM	NM	33.9x
EPS, Ops Diluted	Q1	Q2	Q3	Q4
2023	(0.19)A	(0.37)A	(0.47)A	(0.33)A
2024	(0.67)A	0.02A	(0.16)E	(0.18)E
Prev.		(0.17)E	(0.19)E	(0.20)E
Revenue				
2023	10.0A	0.0A	0.0A	0.0A
2024	0.1A	0.1A	0.0E	0.3E
Prev.		0.0E	0.3E	1.5E

All market data in USD; all financial data in USD; dividends paid in CAD.
Priced as of prior trading day's market close, EST (unless otherwise noted).



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the company emphasized that this is isolated to a single toolbox of tests done by a third party and that their careful audit of the rest of the package did not reveal any other discrepancies.

GeMDAC AdComm tentatively scheduled, and we lean favorably on likelihood of positive vote given ZVRA readthroughs. The GeMDAC AdComm on govorestat in galactosemia is now tentatively scheduled for Oct 9th, giving the company an opportunity to make their case for a complex dataset in a rare disease. Recall that the same newly formed AdComm discussed Zevra's arimoclomol application for NPC disease and [voted 11-5](#) in favor considering the totality of the package, where ZVRA hit on the primary and provided additional confirmatory data to support their application. While there are key differences in the datasets and indications, we believe this supports an increasing likelihood APLT's AdComm will also view govorestat favorably.



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Exhibit 1 - APLT Income Statement

APLT Income Statement (\$ in thousands except price)	2022A	2023A	1Q24A	2Q24A	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Govorestat					-	250	250	49,976	157,686	272,796	379,722	468,976	537,305	597,598	650,958	706,399
Galactosemia		-			-	250	250	39,411	93,486	144,548	189,858	221,747	237,967	252,491	267,598	283,311
SORD		-			-	-	-	10,566	64,200	128,249	189,864	247,229	299,339	345,108	383,359	423,088
AT-001 Royalties													4,236	21,676	53,541	117,537
Milestones		-					-	5,000	30,000	-	5,000	5,000	5,000	-	-	10,000
License Revenue		9,993	190	144	-	-	334	-	-	-	-	-	-	-	-	-
Total revenues, net	-	9,993	190	144	-	250	584	54,976	187,686	272,796	384,722	473,976	546,541	619,274	704,499	833,936
Costs of goods						12	12	6,813	9,647	18,033	23,953	29,897	34,698	38,967	42,681	46,562
Research and development	55,634	53,905	12,217	10,004	10,704	11,775	44,700	54,534	49,081	45,645	47,927	49,844	51,838	53,393	54,995	56,645
Selling, general and administrative	27,316	20,623	9,066	10,580	12,696	15,235	47,577	76,124	98,961	123,701	136,071	142,874	150,018	156,019	160,699	165,520
Total operating expenses	82,950	74,528	21,283	20,584	23,400	27,022	92,290	137,470	157,688	187,379	207,951	222,616	236,554	248,379	258,375	268,727
Income/loss from operations	(82,950)	(64,535)	(21,093)	(20,440)	(23,400)	(26,773)	(91,706)	(82,494)	29,999	85,418	176,771	251,360	309,988	370,896	446,124	565,209
Interest and other income	685	1,372	586	628	833	654	2,701	557	916	1,692	2,108	3,277	4,729	6,376	8,212	10,394
Change in fair value of warrant liabilities	(66)	(56,573)	(63,405)	22,744	-	-	(40,661)	-	-	-	-	-	-	-	-	-
Other income (expense), net	(177)	(27)	(26)	(34)	(34)	(34)	(128)	(128)	(128)	(128)	(128)	(128)	(128)	(128)	(128)	(128)
Net pre-tax income	(82,508)	(119,763)	(83,938)	2,898	(22,601)	(26,153)	(129,794)	(82,065)	30,786	86,982	178,751	254,508	314,589	377,143	454,208	575,475
Income tax provision	-	-	-	-	-	-	-	-	-	-	-	5,090	25,167	52,800	90,842	115,095
Net income (loss)	(82,508)	(119,763)	(83,938)	2,898	(22,601)	(26,153)	(129,794)	(82,065)	30,786	86,982	178,751	249,418	289,422	324,343	363,367	460,380
Earnings per share (non-GAAP)	(\$2.18)	(\$1.42)	(\$0.67)	\$0.02	(\$0.16)	(\$0.18)	(\$0.93)	(\$0.56)	\$0.18	\$0.51	\$1.04	\$1.45	\$1.67	\$1.87	\$2.08	\$2.63
Shares Outstanding (Basic)	37,825	84,244	125,319	143,934	144,634	145,334	139,805	146,834	147,972	148,334	149,472	149,834	150,972	151,334	152,472	152,834
Shares Outstanding (Diluted)	73,641	112,683	147,458	163,267	166,773	167,473	161,243	168,973	170,111	170,473	171,611	171,973	173,111	173,473	174,611	174,973

Source: RBC Capital Markets estimates; APLT company reports



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Exhibit 2 - APLT Pipemile

Milestones		
Product	Event	Timeline
Govorestat	AdComm for govorestat in galactosemia	Oct. 9, 2024
	PDUFA for govorestat in galactosemia	28-Nov-24
	Pre-NDA meeting(s) to discuss SORD accelerated approval	2H24
	EMA decision on govorestat in galactosemia	Early-1Q25
	sNDA submission in SORD	Early-1Q25
AT-001	Data from DPN substudy	2024
	FDA meeting and disclose next steps	2024

Pipeline		
Product	Indication	Status
Govorestat	Galactosemia, SORD, PMM2-CDG	Under Review, Ph.III
AT-001	Diabetic cardiomyopathy	Ph.III
AT-003	Diabetic retinopathy	Ph.I ready

Source: RBC Capital Markets estimates; APLT company reports



Key fundamental questions

Our view

Is the data for govorestat sufficient for an approval in galactosemia?

Despite the rocky regulatory road and miss on the primary endpoint for govorestat in galactosemia, we believe the clear reductions in galactitol – a causative agent of the disease phenotype – combined with functional benefits across nearly all domains, should be sufficient to convince regulators that the drug has a favorable benefit/risk profile in a disease with limited treatment options. We find the explanations for the primary endpoint miss (driven by speech domains which may have been confounded by speech therapy) as plausible, and find the extensive sensitivity analyses, including correlations between galactitol and function, as providing sufficient support, especially at a time the Agency is moving towards greater flexibility for rare disease indications.

Is the initial functional correlation data sufficient to secure an accelerated approval in SORD?

While we acknowledge that the SORD trial was not stopped early for efficacy at the interim, we do see evidence of functional impact, with the ph.III showing a pre-specified correlation between sorbitol reduction and functional trends at 1yr. The fact that all functional domains and patient reported outcomes trend in favor of the drug, coupled with the significant body of evidence sorbitol is the key disease driver, may be sufficient to convince the FDA the accelerated approval pathway should be applied, especially with 2-year confirmatory data on track for early-'25, and we believe the confirmatory data is likely to show clear benefits on key outcome measures, even if not stat. sig.

Is there a sufficient market for a drug with govorestat's profile in these rare diseases?

We see a TAM of ~3k patients each for galactosemia and SORD in the U.S., and given high specialist concentration and overlap in treating physicians, we believe even a smaller company like APLT can execute a successful launch in these rare disease indications by leveraging a small targeted salesforce and premium pricing. While we acknowledge potential challenges such as patient identification – especially in the relatively newer SORD indication – and heterogeneity particularly in galactosemia, detailing around govorestat's potential benefits should grow over time, and we believe there is sufficient KOL receptivity to enable a \$600M+ LT U.S. opportunity.



Key ESG questions

This section is intended to highlight key ESG discussion points relevant to this company, as well as our views on the outlook. Both the questions we highlight and our responses will evolve over time as the dialogue between management, analysts and investors continues to advance. We welcome any feedback on the topics.

Our view

What are the most material ESG issues facing this company?

Like many other early clinical stage biotechs, APLT faces issues such as green laboratory practices and manufacturing, proper clinical trial conduct, data transparency, diversity of the management team, and hiring and maintaining a diverse set of employees. In the future, we would anticipate that the company will also contend with many of the same ESG topics that impact the broader sector, chiefly drug pricing, access to medication, and responsible product marketing

Does the company integrate ESG considerations into its strategy?

ESG is currently not an area of active focus for APLT given its capital constraints and focus on progressing drugs through clinical and regulatory development, which is typical of similarly sized biotech companies.

What is diversity like at the board/management level?

The CEO of APLT is a woman, uncommon for biotech. One out of 5 senior management members is a woman and none are people of color; three out of six board members are women and none are people of color.

Is APLT treating diseases with a significant patient health burden where the potential benefits to patients outweigh the risks?

APLT's clinical programs focus on treating rare genetic diseases where there are no other approved therapies, highlighting a commitment to improving the well-being of underserved patients. As such, we see a high societal value in the company's work.

How will the company ensure access and affordability of its medications?

We acknowledge that rare disease drugs tend to be priced at a premium, making them out of reach without insurance or company support. That said, we expect the company to employ industry-standard, value-based pricing, co-pay cards, and patient outreach programs to help those who need the drugs to be able to access and afford them.

How is APLT managing data transparency and disclosures?

APLT currently releases data through company press releases, presentations, and conferences. We believe that former issues with inconsistent data across presentations appear to have largely been resolved, and have sometimes occurred historically among smaller biotechs running lean operations. We expect additional meaningful disclosures as the company advances its clinical development.

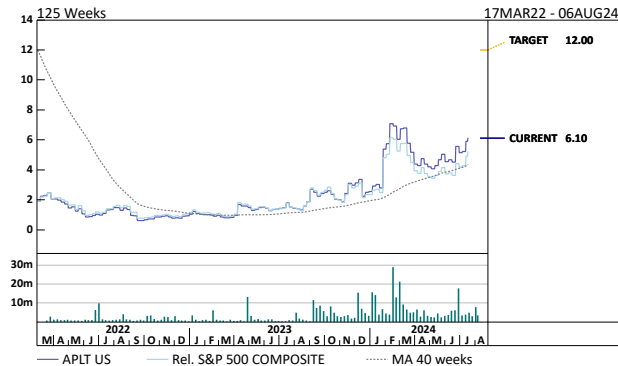


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Target/Upside/Downside Scenarios

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Source: Bloomberg and RBC Capital Markets estimates for Target

Valuation

Our \$12 price target blends DCF (using an 11% discount rate and a 2.5% terminal growth rate) and sales multiple (30x on 2033E adjusted EPS discounted at 11%) analyses – comparable to other commercial stage biotechs. This price target supports our Outperform, Speculative Risk rating. We assign a Speculative Risk qualifier given unpredictability of future revenues and expenses, non-revenue-generating status, and stock price volatility that could result in substantial upside/downside swings not anticipated in our valuation.

Upside scenario

Regulatory success with govorestat in galactosemia and/or SORD, successful completion of the 24-month SORD trial with a hit on the primary endpoint, and potential partnering of the AT-001 asset could all drive upside, in which case we could see the share price approach \$18/sh.

Downside scenario

Failure to secure regulatory approval for govorestat in galactosemia and/or SORD, any unexpected safety signals emerging, or govorestat not achieving clinically meaningful results in the ongoing ph.III SORD trial could drive shares lower, and we see downside as ~\$2/sh.

Investment summary

We like APLT, as we see data from govorestat in galactosemia as likely sufficient to make it over the regulatory line given convincing biomarker improvements and clear trends towards meaningful functional benefits. We believe rare disease flexibility will enable govorestat to make it to the market, where we would expect a rapid pace of uptake. We expect similar dynamics to play out in SORD - where positively trending data with clear biological correlates can potentially enable an accelerated approval. While we acknowledge that there remains regulatory risk and that the benefits may be of uncertain magnitude given less well-defined natural history in these diseases, we believe APLT can ultimately see a \$650M+ out-year revenue opportunity not fully appreciated at current valuations.

Key positives: (1) Govorestat has consistently driven clear improvements on biomarkers of both galactosemia and SORD; (2) Rare disease indications mean we can expect greater regulatory flexibility; (3) Rare disease indication suggests we could see rapid uptake of the drug with a smaller salesforce; (4) No major safety concerns with one completed ph.III and another in progress.

Key risks: (1) Govorestat missed on its primary endpoint in galactosemia and was not successfully stopped at the interim in SORD, adding risk to regulatory interpretation of the totality of the data; (2) Both galactosemia and SORD are newer diseases where patient finding may be required; (3) Slower disease progression and symptom heterogeneity make it more difficult to parse out clinically meaningful benefits.

Key upcoming potential catalysts: (1) AdComm for govorestat in galactosemia (Oct. 9); (2) PDUFA date for govorestat in galactosemia (11/28/24); (3) sNDA submission of govorestat in SORD (early-1Q25); (4) 2yr primary endpoint data from SORD ph.III (early-'25).

Risks to rating and price target

Risks include emergence of unexpected safety signals, failure of clinical trials to demonstrate sufficient efficacy to warrant continued development or regulatory submission, failure to successfully commercialize its products, inability to maintain a salesforce, entry of generic competitors, failure to garner regulatory approval, failure to manufacture sufficient material in accordance with regulatory standards, counterparty risk with respect to successful ex-US commercialization, and an inability to finance ongoing operations given significant outlays required for commercialization.



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Company description

APLT is a clinical stage biotech that is developing aldose reductase inhibitors to treat primary rare genetic diseases, though the company has explored larger indications such as diabetic cardiomyopathy. APLT was founded in 2016. The company's lead asset is govorestat (AT-007), an aldose reductase inhibitor that has completed ph.III trials in some indications and is being explored for galactosemia, SORD deficiency, and PMM2-COG. The company is headquartered in New York, New York.

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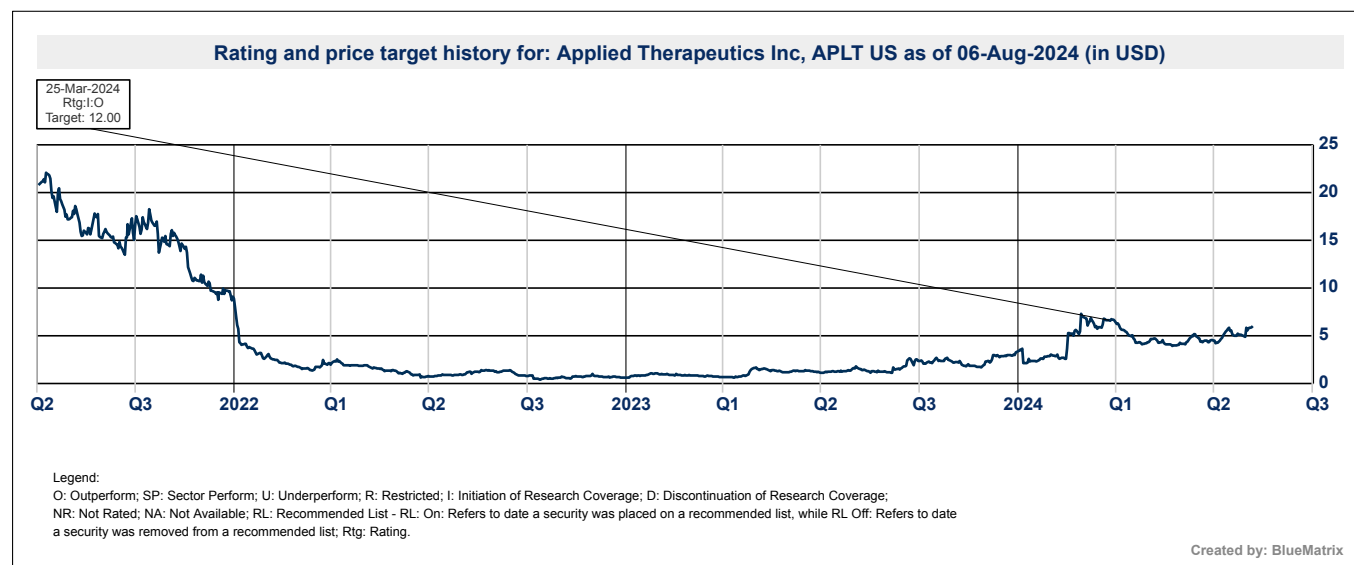
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Valuation

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